(iii) *Limitations.* Implant subcutaneously in ear only. Not for use in animals intended for subsequent breeding or in dairy animals.

[60 FR 4376, Jan. 23, 1995, as amended at 61 FR 29480, June 11, 1996; 61 FR 41499, Aug. 9, 1996; 62 FR 28629, May 27, 1997; 64 FR 42597, Aug. 5, 1999; 64 FR 48294, Sept. 3, 1999; 65 FR 10706, Feb. 29, 2000; 65 FR 26748, May 9, 2000; 65 FR 45879, July 26, 2000; 65 FR 70663, Nov. 27, 2000]

§ 522.2478 Trenbolone acetate and estradiol benzoate.

(a) *Sponsor.* See 000856 in § 510.600(c) of this chapter.

(b) *Related tolerance.* See §§ 556.240 and 556.739 of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Steers*—(i) *Amount.* 200 milligrams of trenbolone acetate and 28 milligrams of estradiol benzoate (one implant consisting of 8 pellets, each pellet containing 25 milligrams of trenbolone acetate and 3.5 milligrams of estradiol benzoate) per animal.

(ii) *Indications for use.* For increased rate of weight gain and improved feed efficiency in steers fed in confinement for slaughter.

(iii) *Limitations.* Implant subcutaneously in ear only.

(2) *Heifers*—(i) *Amount.* 200 milligrams of trenbolone acetate and 28 milligrams of estradiol benzoate (one implant consisting of 8 pellets, each pellet containing 25 milligrams of trenbolone acetate and 3.5 milligrams of estradiol benzoate) per animal.

(ii) *Indications for use.* For increased rate of weight gain in heifers fed in confinement for slaughter.

(iii) *Limitations.* Implant subcutaneously in ear only. Not for dairy or beef replacement heifers.

[61 FR 14482, Apr. 2, 1996, as amended at 61 FR 29479, June 11, 1996; 63 FR 63789, Nov. 17, 1998; 64 FR 18573, Apr. 15, 1999]

§ 522.2483 Sterile triamcinolone acetonide suspension.

(a) *Specifications.* Each milliliter of suspension contains 2 or 6 milligrams triamcinolone acetonide.

(b) *Sponsor.* See 000010 and 053501 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*—(i) *Dogs and cats—(a) Intramuscular or subcutaneous.* Single injection of 0.05 to 0.1 milligram (mg.) per pound of body weight in inflammatory, arthritic, or allergic disorders. Single injection of 0.1 mg. per pound of body weight in dermatologic disorders. If symptoms recur, the dose may be repeated, or oral corticosteroid therapy may be instituted.[1]

(b) Intralesional. 1.2 to 1.8 mg., divided in several injections, spaced around the lesion at 0.5 to 2.5 centimeters apart depending on the size. At any one site the dose injected should not exceed 0.6 mg. and should be well into the cutis to prevent rupture of the epidermis. When treating animals with multiple lesions, do not exceed a total dose of 6 mg.

(c) Intra-articular and intrasynovial. Single injection of 1 to 3 mg. dose, dependent on size of joint and severity of symptoms. After 3 or 4 days, repeat dosage if indicated. If initial results are inadequate or too transient, dosage may be increased, not to exceed 3 mg.

(ii) *Horses—(a) Intramuscular or subcutaneous.* Single injection of 0.01 to 0.02 mg. per pound of body weight. Usual dose, 12 to 20 mg.

(b) Intra-articular and intrasynovial. Single injection of 6 to 18 mg. dose, dependent on size of joint and severity of symptoms. After 3 or 4 days, repeat dosage if indicated. If initial results are inadequate or too transient, dosage may be increased, not to exceed 18 mg.

(2) *Indications for use.* Treatment of inflamation and related disorders in dogs, cats, and horses;[1] and management and treatment of acute arthritis and allergic and dermatologic disorders in dogs and cats.

(3) *Limitations.* (i) Do not use in viral infections. With bacterial infections, appropriate antibacterial therapy should be used.

(ii) Do not use in animals with tuberculosis, chronic nephritis, or cushingoid syndrome, except for emergency therapy.

(iii) Not for use in horses intended for food.

[1] These conditions are NAS/NRC reviewed and are deemed effective. Applications for these uses need not include the effectiveness data specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(iv) Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.

(v) Do not use in the treatment of laminitis.

(vi) Intra-articular injection in equine leg injuries may produce osseous metaplasia.

(vii) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[43 FR 4976, Feb. 7, 1978, as amended at 50 FR 41490, Oct. 11, 1985; 52 FR 1903, Jan. 16, 1987; 53 FR 40728, Oct. 18, 1988; 62 FR 35077, June 30, 1997]

§ 522.2582 Triflupromazine hydrochloride injection.

(a) *Specifications.* Triflupromazine hydrochloride injection contains 20 milligrams of triflupromazine hydrochloride in each milliliter of sterile aqueous solution.

(b) *Sponsor.* See No. 053501 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is used in dogs, cats, and horses to relieve anxiety and to help control psychomotor overactivity as well as to increase the tolerance of animals to pain and pruritus. The drug is indicated in various office and clinical procedures which require the aid of a tranquilizer, antiemetic, or preanesthetic.[1]

(2) The drug is administered to dogs either intravenously at a dosage level of 0.5 to 1 milligram per pound of body weight daily, or intramuscularly at a dosage level of 1 to 2 milligrams per pound of body weight daily. It is administered to cats intramuscularly at a dosage level of 2 to 4 milligrams per pound of body weight daily. It is administered to horses intravenously or intramuscularly at a dosage level of 10 to 15 milligrams per 100 pounds of body weight daily to a maximum dose of 100 milligrams.[1]

(3) Not for use in horses intended for food.[1]

(4) Do not use in conjunction with organophosphates and/or procaine hydrochloride, because phenothiazines may potentitate the toxicity of organophosphates and the activity of procaine hydrochloride.[1]

(5) Federal law restricts this drug to use by or on the order of a licensed veterinarian.[1]

[40 FR 13858, Mar. 27, 1975, as amended at 50 FR 41490, Oct. 11, 1985]

§ 522.2610 Trimethoprim and sulfadiazine sterile suspension.

(a)(1) *Specifications.* Each milliliter of sterile aqueous suspension contains 240 milligrams (40 milligrams of trimethoprim and 200 milligrams of sulfadiazine).

(2) *Sponsor.* See 000061 and 000856 in § 510.600(c) of this chapter.

(3) *Conditions of use*—(i) *Dosage.* One milliliter (40 milligrams of trimethoprim and 200 milligrams of sulfadiazine) per 20 pounds (9 kilograms) of body weight per day.

(ii) *Indications.* For dogs for treatment of acute urinary tract infections, acute bacterial complications of distemper, acute respiratory tract infections, acute alimentary tract infections, and acute septicemia due to *Streptococcus zooepidemicus.*

(iii) *Limitations.* For subcutaneous use in dogs only; administer once every 24 hours, or for severe infections, after an initial dose, administer half the normal daily dose every 12 hours; continue therapy 2 to 3 days after clinical signs of infection have subsided; if no improvement is seen in 3 to 5 days, reevaluate diagnosis; injection may be used alone or in conjunction with oral dosing; not recommended for use for more than 14 days; a complete blood count should be done for prolonged use; Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(b)(1) *Specifications.* Each milliliter of sterile aqueous suspension contains 480 milligrams (80 milligrams of trimethoprim and 400 milligrams of sulfadiazine (as the sodium salt)).

[1] These conditions are NAS/NRC reviewed and are deemed effective. Applications for these uses need not include the effectiveness data specified by § 514.111 of this chapter, but may require bioequivalency and safety information.